



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

m38347

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

## WARNING LETTER

JUN 9 2000

### CERTIFIED MAIL-RETURN RECEIPT REQUESTED

Vachakan H. Khoie, President  
American Dent-All, Inc.,  
5140 San Fernando Road  
Glendale, CA 92104

W/L 60-00

Dear Mr. Khoie:

During an inspection of your firm located in Santa Fe Springs, California, conducted from April 19 to 24, 2000, our Investigators determined that your firm manufactures dental alloy products. Dental alloy products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act.

Our inspection disclosed that these devices are adulterated within the meaning of Section 510(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, and storage are not in conformance with the Good Manufacturing Practice (GMP) requirements for the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and maintain a device master record for the dental alloy products that includes a compilation of records containing procedures and specifications for the finished device [21 CFR 820.181].
2. Failure to maintain device history records for dental alloy products to demonstrate that the devices are manufactured in accordance with the device master record [21 CFR 820.184].
3. Failure to follow procedures to control all documents that are required by the Quality System Regulation [21 CFR 820.40]. For example, there was no documented evidence to support changes made to your dental alloy products labeling and labeling specifications.

4. Failure to control procedures to ensure that all purchased or otherwise received product and services conform to specified requirements [21 CFR 820.50]. For example, there is no documented evidence demonstrating any evaluations of suppliers of components and other materials.
4. Failure to establish and implement plans that describe or reference the design and development activities of devices and define responsibility for implementation [21 CFR 820.30 (b)].
5. Failure to control procedures for management reviews [21 CFR 820.20(c)]. For example, there was no documented evidence to show that management reviews are conducted at your defined intervals.

We acknowledge that you have submitted a written response dated April 28, 2000, addressing the observations noted by our investigators during their inspection. Your letter describes the proposed corrective measures that your company intended to implement, however, no supporting documents describing the specific steps taken by your firm were included with your letter. Your letter also indicated that all corrections would be implemented by May 26, 2000. To date, our office has not received any further correspondence concerning the corrective measures undertaken by your company to ensure compliance with Quality System Regulation.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Exportability will be approved until the violations related to the subject devices have been corrected.


You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Please submit your response to:

Director, Compliance Branch  
Food and Drug Administration  
19900 MacArthur Boulevard, Suite 300  
Irvine, CA 92612-2445

Sincerely,

  
Thomas L. Sawyer  
Acting District Director

cc: State Department of Public Health  
Environmental Health Services  
Attn: Chief, Food and Drug Branch  
601 North 7<sup>th</sup> Street, MS-357  
Sacramento, CA 94234-7320